

REMARKS

Applicants have carefully reviewed the Office Action mailed June 14, 2006. By this Response to Office Action, claims 1, 11-15, 18, 25, 29, 36-37, 47-48, 52, 54, and 61-62 are amended, claims 68-77 are added, claims 44-46 and 59 are withdrawn, and claims 28, 31, and 53 are cancelled.

Applicants have made the above-identified modifications to the claims solely to advance prosecution of the present application and to obtain allowable claims at the earliest possible date. Accordingly, no admission may be inferred from these claim modifications. Applicants expressly reserve the right to pursue the originally filed claims in the future. Additionally, Applicants submit that the modifications made herein introduce no new matter.

The following remarks are respectfully submitted.

Examiner's Decision To Examine the Claims of Group I and Group II Together

Applicants thank Examiner for searching and examining the claims in Groups I and II rather than only those in Group I. As mentioned above, Applicants have withdrawn the claims of Group III.

Independent Claim 1 and Its Dependent Claims

Applicants respectfully submit that amended claim 1 is novel over U.S. Patent No. 3,292,613 to MacLeod ("MacLeod '613") and patentable over all of the cited art. Amended claim 1 recites an element that is "adapted to generate pressure for between 1 and 20 seconds and to release pressure for between 2 and 15 seconds." Neither MacLeod '613 nor any of the other cited references disclose such an element.

MacLeod '613 discloses providing short pulses of pressure—pulses in which both pressure generation and pressure release are completed in time for each heart beat. For instance, MacLeod '613 states that "[t]he pressure can be synchronized to the heart beat." (MacLeod '613 at 5:9) MacLeod '613 also discloses applying pulses "less or more frequently and in regular multiples of a heart beat," but such pulses have the same short duration (MacLeod '613 at 5:10-

11.) With respect to systems like that of MacLeod '613, the specification of the present application states,

In a number of earlier known systems in which an oscillating pressure was applied to a patient, it was thought best to vary pressure in time with the heart beat. The present inventors have found that a longer period to the oscillation is better.

(Page 21, lines 15-17.) Amended claim 1 recites such a longer period of oscillation, with pressure generation lasting for between 1 and 20 seconds and pressure release lasting for between 2 and 15 seconds. MacLeod '613 does not disclose an element adapted to generate such pulses of pressure. Accordingly, Applicants respectfully submit that amended claim 1, and its dependent claims, are novel over MacLeod '613.

Moreover, Applicants also respectfully submit that amended claim 1 is nonobvious. In rejecting claims having language related to the duration of the pressure pulses, Examiner stated that "the claimed time intervals are well within the realm of one ordinary skill in the art, and do not provide any unobvious result." Applicants respectfully disagree with this statement.

Subjecting a local region of the body to pulses of pressure like those of amended claim 1 produces remarkable increases in blood velocity within that region. For instance, according to the specification, "it has been found that a preferred embodiment can improve blood velocity by up to at least 30% in the brachial artery." (Page 15, lines 9-10.) Likewise, the application states,

In experiments, an average of at least 50% increase in blood velocity and an increase of 200% in a single subject have been witnessed. By pulsating the pressure, it is believed to facilitate the immediate and repeated increase of blood velocity without inducing a reflex constriction as a result of the venus pooling.

(Page 15, lines 10-14.) The application further states,

Figure 4 shows a detailed one minute recording. The negative pressure is built up for 10 seconds and released for 7 seconds (upper panel). The blood velocity in the brachial artery is measured outside the pressure chamber 4. The blood velocity increases to a certain point, about -25 mmHg (-3.4 kPa), before it drops. This is thought to be due to a reflex constriction of the arteries because of the venus pooling. Letting the pressure drop again, facilitates the immediate and repeated increase of blood velocity without the reflex restricting the blood flow as can happen with a constant negative pressure.

(Page 31, line 21 through page 32, line 2.) The test trial discussed on pages 36-38 of the specification provides even further evidence of amended claim 1's nonobviousness. Because providing pulses of the claimed duration is not within the realm of ordinary skill in the art, and because the results produced are not obvious, Applicants respectfully submit that amended claim 1 is nonobvious. Accordingly, Applicants respectfully request that Examiner allow amended claim 1 and all of its dependent claims (2-24, and 68-77).

Independent Claim 25 and Its Dependent Claims

Applicants respectfully submit that amended claim 25 is novel over MacLeod '613 for the reasons set forth above in connection with claim 1. Amended claim 25 recites that "each pulse of pressure is generated for between 1 and 20 seconds and released for between 2 and 15 seconds." MacLeod '613 does not disclose this.

Moreover, Applicants respectfully submit that amended claim 25 is novel over U.S. Patent No. 3,094,983 to MacLeod ("MacLeod '983"). MacLeod '983 states that "it has been found desirable that the cycle of pressure variation in the chamber should be similar or related to that of the heart." (MacLeod '983 at 1:31-33.) As mentioned above, such short pulses are materially different from pulses in which pressure generation is for between 1 and 20 seconds and pressure release is for between 2 and 15 seconds. Also, even though MacLeod '983 states that "in the prior art, where gas has been used, the rate of cyclic operation has been usually 15 to 50 seconds or more per cycle" (MacLeod '983 at 34-36), this statement alone does not disclose generating pulses of pressure having the specific pressure generation and pressure release durations recited in amended claim 25 with sufficient specificity for anticipation. Accordingly, Applicants respectfully submit that amended claim 25, and its dependent claims, are novel over MacLeod '983.

Additionally, Applicants respectfully submit that amended claim 25, along with all its dependent claims, is nonobvious for the reasons set forth above in connection with claim 1. Amended claim 25 recites generating specific pulses of pressure that are not within the realm of ordinary skill in the art, and the results produced are not obvious. Accordingly, Applicants respectfully request that Examiner allow amended claim 25 and all of its dependent claims (26-27, 29-30, and 32-43).

Independent Claim 47

Applicants respectfully submit that amended claim 47 is novel over U.S. Patent No. 3,878,839 to Norton (“Norton”) and patentable over all of the cited art. Amended claim 47 recites

a barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin, the barrier layer defining *an inner region* within the pressure chamber for receiving the limb which is separated from *an outer region* having a flow of liquid within the chamber,

. . . .

an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin, *the element or means for generating negative pressure being in communication with the inner region but not with the outer region.*

Norton discloses nothing that can generate negative pressure by being in communication with an inner region but not with an outer region. Rather, Norton states,

Thus, a continuous suction can be created in the space between the limb and the sealed container by an external evacuation device. One method of achieving this is to enclose the legs and housing units of the system by a vacuum enclosure 84 as shown by the dashed line in FIG. 13

(Norton at 11:19-24.) Norton’s vacuum enclosure (84 in FIG. 13) surrounds and is in communication with the entire housing units rather than with only the space between the sealed container (90 in FIG. 14) and the patient’s legs. Thus, Norton’s device cannot anticipate amended claim 47. Moreover, such an enclosure that encapsulates the entire housing units would be unwieldy compared with a relatively smaller element or means in communication with the inner region but not with the outer region.

Norton also discloses two other ways to maintain a seal between the sealed container and the patient’s limb, neither of which anticipate, or render obvious, amended claim 47. First, Norton states,

Such seal can be maintained by the use of an adhesive compound on the surface of the sealed container between the container and the limb. However, such a method may be impractical or inappropriate in many situations.

(Norton 11:8-11.) Amended claim 47 is clearly patentable over such a device that uses adhesive to create a seal. Second, Norton discloses a “self-evacuation system” (see FIG. 14) in which the mechanism that produces the pressure cycle also expels air from between the sealed enclosure and the leg. Amended claim 47 is patentable over this device in that amended claim 47 includes a separate element or means for maintaining the barrier layer in contact with the area of skin. For these reasons, Applicants respectfully submit that amended claim 47 is both novel and nonobvious over Norton. Accordingly, Applicants respectfully request that Examiner allow amended claim 47.

Independent Claim 48 and Its Dependent Claim

Applicants respectfully submit that amended claim 48 is nonobvious for the reasons set forth above in connection with claim 1. Amended claim 48 recites generating and releasing negative pressure in specific intervals not within the realm of ordinary skill in the art, and the results produced are not obvious. Accordingly, Applicants respectfully request that Examiner allow amended claim 48 and its dependent claim (49).

Independent Claim 50 and Its Dependent Claim

Applicants respectfully submit that claim 50 is nonobvious for the reasons set forth above in connection with claim 1. Claim 50 recites generating and releasing negative pressure in specific intervals not within the realm of ordinary skill in the art, and the results produced are not obvious. Accordingly, Applicants respectfully request that Examiner allow claim 50 and its dependent claim (51).

Independent Claim 52 and Its Dependent Claims

Applicants respectfully submit that amended claim 52 is novel over MacLeod '613 for the reasons set forth above in connection with claim 1. Amended claim 52 recites that “alternately generating negative pressure for a predetermined time interval of 1 to 20 seconds and releasing negative pressure for a predetermined time interval of 2 to 15 seconds within the chamber.” MacLeod '613 does not disclose this.

Additionally, Applicants respectfully submit that amended claim 52, along with all its dependent claims, is nonobvious for the reasons set forth above in connection with claim 1. Amended claim 52 recites generating and releasing pressure in specific intervals not within the realm of ordinary skill in the art, and the results produced are not obvious. Accordingly, Applicants respectfully request that Examiner allow amended claim 52 and all of its dependent claims (54-58 and 60).

Independent Claim 61

Applicants respectfully submit that amended claim 61 is novel over Norton and patentable over all of the cited art. Amended claim 61 recites,

introducing a positive pressure into the gas pocket for between 2 and 15 seconds at predetermined time intervals to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket.

Neither Norton nor any of the cited art disclose such a step. The specification describes benefits associated with this step as follows:

When the pressure drops back to zero (relative to atmospheric pressure), the veins constrict and the blood is forced towards the direction with the lowest resistance to flow. The venous valves will effectively force the blood in the direction towards the heart only. If a positive pressure is added the transmural pressure will drop. The intramural pressure is much larger in the arteries. This leads to a relative larger constriction of veins compared to arteries, and the veins are “emptied” of blood. The veins are now ready to receive more blood, and the pressure starts to drop again. The microvasculature capillaries also appear to be affected and there is also a possibility that the lymphatic system is affected too, and that lymph flow is increased. Lymphatic circulation is believed to be affected by the pulsating pressure in the same way as the veins because the vessels also have one-way valves. As the vessel walls are even thinner than in the veins, a system operating on the lymphatic system alone may be utilised by operating at lower pressures (including positive pressures) but following the same pulsating mode, thereby minimizing the effects on the arteries/veins (because increased blood flow can have a negative effect on oedema etc.).

(Page 14, lines 18-25.) For this reason, Applicants respectfully submit that amended claim 61 is both novel and nonobvious. Accordingly, Applicants respectfully request that Examiner allow amended claim 61.

Independent Claim 62 and Its Dependent Claims

Applicants respectfully submit that amended claim 62 is novel over MacLeod '613 for the reasons set forth above in connection with claim 1. Amended claim 62 recites that "generating pulsating pressure includes alternately generating pressure for between 1 and 20 seconds and releasing pressure for between 2 and 15 seconds." MacLeod '613 does not disclose this.

Additionally, Applicants respectfully submit that amended claim 62, along with all its dependent claims, is nonobvious for the reasons set forth above in connection with claim 1. Amended claim 56 recites alternately generating and releasing pressure in specific intervals not within the realm of ordinary skill in the art, and the results produced are not obvious. Accordingly, Applicants respectfully request that Examiner allow amended claim 62 and all of its dependent claims (62-67).

Conclusion

In view of the foregoing, Applicants respectfully submit that this application stands in condition for allowance. Applicants respectfully request favorable consideration and prompt allowance. Applicants believe that the payment accompanying this submission covers the excess claim fees stemming from the addition of claims 68-77. However, the Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 06-1910. Examiner is invited to telephone the undersigned if believed to be useful to advance prosecution.

Respectfully submitted,

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